DEC 16 2011

K110881

5. 510(k) Summary

[as required by 807.92(c)]

A. **Applicant:**

-Company name: DONG IL TECHNOLOGY LTD.

-Address:215-6, Bugyang-dong, Hwaseong-si, Gyeonggi-do, 445-040, Republic of Korea

-Tel : +82(31)356-7114 Fax : +82(31)357-261http://www.dongiltech.co.kr

-Contact person: **Peter Chung** 412-687-3976

-Date: **Mar 16,2011**

B. Proprietary and Established Names:

Trade Name:Sonic Surgeon 300

Common Name:.Bone cutting instrument and accessories

Regulation Name: Sonic surgical instrument and accessories/attachments

Regulatory Classification: 2, Dental,

Product Code: DZI

C. legally marketed predicate devices : Piezosurgery(K043408)

D. Device Description,

Sonic Surgeon 300is an ultrasound generator for use in dental surgery.And this device is used for surgical procedures, including osteotomy, osteoplasty, periodontal surgery and implantation.Boost Mode can be used for mechanical ultrasound treatment in prophylaxis, periodontics or endodontics.

The tips can easily be changed during the treatment and can also be cleaned and autoclaved

Material for sonic surgeon 300 are as follows

Component	material
Enclosure (Generator Unit, Foot Switch)	PC ABS
Hose, and seals	Silicone
Enclosure (Handpiece)	PES
Tip	SUS

E. Intended use

Ultrasonic Surgical Unitis a piezoelectric device for bone surgery that enables osteotomy and osteoplasty techniques to be applied to in dental use

F.Technological Characteristics:

a). Ultrasonic Surgical Unit has the following features

The Ultrasonic Surgical Unittransforms generated ultrasonic(26±3kHz) energy to the kinetic energy and transmitsit to the tip.

The generator of the Ultrasonic Surgical Unit performs automatic tuning of the operating frequency, the efficiency of the piezoelectric transducer in the handpiece.

This feature makes it possible to bone cutting, grinding and drilling action.

b). Our device is very similar with predicate device, **Piezosurgery(K043408), because** Sonic Surgeon 300 has the following identical characteristics ; intended use, sterilization method , used material , electronic input power , frequency, and power output

G. Performance (Safety and Effectiveness Information)

TheUltrasonic Surgical Unit has been manufactured and tested to meet the safety requirements of IEC. The Ultrasonic Surgical Unit complies with IEC 60601-1Medical electrical equipment - Part 1: Generalrequirements for safety and IEC 60601-1-2:2001, Medical electrical equipment - Part 1: Generalrequirements for safety - Collateral standard: Electromagnetic compatibility -Requirements and tests.

I.Conclusion:

The performance tests demonstrated thatUltrasonic Surgical Unitperforms in a substantially equivalent manner to the predicate device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dong IL Technology Limited
C/O Mr. Peter Chung
Submission Correspondent
300 Atwood
Pittsburgh, Pennsylvania 15213

DEC 16 2011

Re: K110881
Trade/Device Name: Ultrasonic Surgical Unit
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: II
Product Code: DZI
Dated: November 14, 2011
Received: December 13, 2011

Dear Mr. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K110881

Device Name: Ultrasonic Surgical Unit

Indications For Use:
Ultrasonic Surgical Unit is a piezoelectric device for bone surgery that enables osteotomy and osteoplasty techniques to be applied to in dental use.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110881